4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1999]

Merck Sharp & Dohme Corp.; Withdrawal of Approval of New Drug Applications for VIOXX (Rofecoxib) Tablets and Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug applications (NDAs) for VIOXX (rofecoxib) Tablets, 12.5 milligrams (mg), 25 mg, and 50 mg, and VIOXX (rofecoxib) Suspension, 12.5 mg/5 milliliter (mL) and 25 mg/5 mL, held by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., P.O. Box 100, 1 Merck Dr., Whitehouse Station, NJ 08889 (Merck). Merck has voluntarily requested that FDA withdraw approval of these applications and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA approved VIOXX (rofecoxib) Tablets (NDA 21042 and NDA 21647) and VIOXX (rofecoxib) Suspension (NDA 21052) for the following indications:

- For relief of the signs and symptoms of osteoarthritis.
- For relief of the signs and symptoms of rheumatoid arthritis in adults.
- For relief of the signs and symptoms of pauciarticular or polyarticular course juvenile rheumatoid arthritis in patients 2 years and older and who weigh 10 kg (22 lbs) or more.

- For the management of acute pain in adults.
- For the treatment of primary dysmenorrhea.
- For the acute treatment of migraine attacks with or without aura in adults.

On September 27, 2004, Merck informed the Agency it had halted the Adenomatous Polyp Prevention on VIOXX (APPROVe) trial due to an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in patients taking VIOXX (rofecoxib) compared to those taking placebo. On September 30, 2004, Merck voluntarily withdrew VIOXX from the U.S. market. In early 2005, FDA conducted a comprehensive review of the approved cyclooxygenase-2 (COX-2) selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs) and the risk of adverse cardiovascular events. On April 6, 2005, after holding a joint meeting of the Arthritis and Drug Safety and Risk Management Advisory Committees, FDA issued a decisional memorandum summarizing the Agency's analysis and recommendations regarding the NSAIDs that were the subject of the review (https://www.fda.gov/media/74279/download). In that report, FDA made various recommendations, including modifications to the safety information in the labeling of approved COX-2 selective NSAIDs, including VIOXX. On June 3, 2005, Merck subsequently requested FDA's input on the content of potential supplemental NDAs to support labeling changes, in the event that Merck decided to bring the drug back to the U.S. market. On December 12, 2005, FDA identified certain safety analyses and other information that would be required in support of such supplemental NDAs.

In Merck's letter requesting withdrawal of VIOXX, Merck summarized its views of the reasons for withdrawal of approval as follows. Merck ultimately made a business decision not to recommence distribution of VIOXX in the United States and, therefore, did not conduct the additional analyses or submit supplemental NDAs supporting the reintroduction of VIOXX. In light of the company's commercial decision not to reintroduce VIOXX to the U.S. market, Merck has requested that FDA withdraw approval of NDA 21042, NDA 21052, and NDA 21647

for VIOXX tablets and suspension.

FDA has determined that withdrawal of these NDAs under § 314.150(d) (21 CFR 314.150(d)) is appropriate, because Merck did not provide the additional information necessary to reintroduce VIOXX (rofecoxib) to the U.S. market that FDA requested in its December 12, 2005, correspondence. On October 7, 2021, Merck requested that FDA withdraw approval of NDA 21042, NDA 21052, and NDA 21647 for VIOXX (rofecoxib) under § 314.150(d) and waived its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 21042 and NDA 21647 for VIOXX (rofecoxib) Tablets, 12.5 mg, 25 mg, and 50 mg, and NDA 21052 for VIOXX (rofecoxib) Suspension, 12.5 mg/5 mL and 25 mg/5 mL, and all amendments and supplements thereto, are withdrawn under § 314.150(d). Distribution of VIOXX (rofecoxib) Tablets, 12.5 mg, 25 mg, and 50 mg, and VIOXX (rofecoxib) Suspension, 12.5 mg/5 mL and 25 mg/5 mL, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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